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Re-evaluation Note REV2017-11

Special Review of Hexazinone: Proposed Decision for Consultation

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1.0 Introduction

Pursuant to subsection 17(2) of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA) has initiated a special review of pest control products containing hexazinone based on the decision taken by Norway in 1998 (Rotterdam Convention, 2001). The initiation of the special review under the *Pest Control Products Act* was announced in December 2013 (Canada, 2013).

Pursuant to subsection 18(4) of the *Pest Control Products Act*, the PMRA has evaluated the aspects of concern that prompted the special review of pest control products containing hexazinone.

2.0 Uses of Hexazinone in Canada

Hexazinone has been registered in Canada since 1977. It is registered for the control of broad leaf weeds and woody plants on lowbush blueberry, highbush blueberry, alfalfa grown for seeds and forage, woodland management areas (in reforestation areas and sites to be established as Christmas tree plantations prior to planting conifers) and Christmas tree plantations. The hexazinone re-evaluation was completed in 2009 (Canada, 2009). Appendix I lists all hexazinone products that are currently registered under the *Pest Control Products Act*. The proposed special review decision is applicable for all registered pest control products containing hexazinone.

3.0 Aspects of Concern that Prompted the Special Review

Based on the review of the Norwegian decision (Rotterdam Convention, 2001), the PMRA has identified the aspects of concern that prompted the special review of hexazinone as:

- Persistence, mobility, leaching to groundwater
- Potential risk to algae.

4.0 PMRA Evaluation of the Aspects of Concern that Prompted the Special Review

Following the initiation of the special review of hexazinone, the PMRA requested information related to the aspects of concern from provinces and other relevant federal departments and agencies, in accordance with subsection 18(2) of the *Pest Control Products Act*. Information related to water monitoring for hexazinone was received and was considered in the special review.

In order to evaluate the aspects of concern for hexazinone, the PMRA has considered currently available relevant information (for example, environmental fate and toxicity information, available Canadian and American water monitoring data, as well as water modelling).

No information related to the aspects of concern was identified in the Canadian incident report database.

4.1 Persistence, Mobility and Leaching to Groundwater

The PMRA has considered the transformation and mobility of hexazinone (Canada 2007, USEPA 2015a). Hexazinone has a very high solubility, a relatively low vapor pressure (1.9×10^{-7} mmHg), and a very low Henry's Law Constant (2×10^{-12} atm-m^3/mol). Hexazinone is not expected to volatilize substantially from wet/moist surfaces. Hexazinone has a low potential for bioaccumulation based on its log K_{ow} of 1.18.

Hexazinone is stable to hydrolysis under normal environmental conditions and stable to aqueous photolysis. Degradation in aerobic soil was mainly as a result of microbiological activity, and half-lives were reported to be 216 and 1440 days in non-sterile and sterile sandy loam soils, respectively. Hexazinone had reported half-lives of 230 days and >1500 days when applied to non-sterile and sterile sediment pond water, respectively. Aerobic aquatic metabolism resulted in a half-life of >2 months.

In leaching/adsorption/desorption studies, it was found that hexazinone weakly adsorbed to sandy loam and silt loam soil, and strongly adsorbed to loam soil. Furthermore, it was found that hexazinone is immobile to mobile in soil. Field dissipation studies in the United States indicated that hexazinone did not move below the top 30 cm of the soil. A forestry dissipation study indicated that hexazinone leached to a depth of >30 cm.

Based on the laboratory data and confirmed by field and forestry data, hexazinone is persistent and mobile in soil and aquatic environments.

Residues of hexazinone in groundwater were estimated using modelling. The refined estimated groundwater concentrations of hexazinone plus its transformation products were 773 µg/L for acute exposures and 564 µg/L for chronic exposures (USEPA 2015b).

Groundwater monitoring data from Canada show that hexazinone was detected at much lower concentrations. The highest concentration of hexazinone detected in Canadian groundwater was 8.9 µg/L.

4.1.1 Drinking Water Risk Assessment

In addition to assessing the potential leaching of hexazinone to groundwater, the PMRA conducted a drinking water risk assessment to determine whether exposure to hexazinone through Canadian groundwater presents a risk of concern.

An acute reference dose (ARfD) for hexazinone of 0.1 mg/kg bw/day for females 13-49 years of age, based on a no observed adverse effect level (NOAEL) of 10 mg/kg bw/day and a composite assessment factor of 100, was selected for the acute risk assessment. An acceptable daily intake (ADI) for hexazinone of 0.1 mg/kg bw/day, based on a NOAEL of 10 mg/kg bw/day and a composite assessment factor of 100, was selected for the chronic assessment.

For the assessment of hexazinone, the developmental and reproductive effects that would trigger an additional safety factor were taken into consideration. The hexazinone database contains the full complement of required studies including developmental studies in rats and rabbits, and a reproductive study in rats. There was no evidence of reproductive toxicity or increased

susceptibility of fetuses or offspring compared to parental animals in the available studies. There was evidence of a serious effect (malformation) in the rat developmental toxicity study. However, this effect occurred in the presence of maternal toxicity, at the highest dose tested, which approached the limit dose. The reference doses used for the dietary risk assessment and the uncertainty factor of 100-fold (10-fold for intra-species variation, 10-fold for inter-species extrapolation) are considered protective of any potential toxicity, as there were no residual uncertainties with respect to the completeness of the data, or with respect to potential toxicity to infants and children. The selection of these endpoints provides a significant margin to the serious effect observed in the rat developmental toxicity study. Therefore, an additional factor was not required.

Acute and chronic drinking water exposure was addressed by incorporating modelled estimated environmental concentrations of hexazinone into the acute and chronic dietary risk assessment (food plus drinking water). Acute aggregate exposure from food and water (assuming 773 µg a.i./L in drinking water), represented 41.8% of the ARfD, which is not of concern. Similarly, chronic aggregate exposure for food and water (assuming 564 µg a.i./L in drinking water) represented up 44.3% of the ADI for all population subgroups, which is also not of concern. The estimated levels of hexazinone in drinking water considered in the assessment far exceed the actual levels detected in Canadian groundwater (maximum of 8.9 µg/L). Thus, the assessment is considered conservative and protective.

The PMRA follows a risk-based scientific approach in determining the risk to human health from pesticides in drinking water. This approach takes into consideration both the estimated level in drinking water sources (exposure) and the toxicity of the pesticide. Based on the drinking water risk assessment of hexazinone, the PMRA concludes that there are no acute or chronic risks of concern from groundwater under the current conditions of use.

The labels of all registered end use products containing hexazinone currently include an environmental hazard statement to reduce the potential for leaching of hexazinone into groundwater. No additional risk mitigation measures are proposed.

4.2 Toxicity to Algae

Algae could be exposed to hexazinone through spray drift or run-off. Hexazinone is an herbicide and is expected to be toxic to algae. The most sensitive endpoint for algae is *Selenastrum capricornutum* with an EC_{50} value of 0.007 mg/L based on cell density (USEPA 2015a).

In order to characterize potential risk to algae, expected environmental concentrations (EECs) were calculated for direct application over a body of water at the maximum application rates (1 to 4.32 kg a.i./ha). The determined EEC values were in the range of 0.13 to 0.54 mg a.i./L at water depth of 80 cm. Risk quotients (RQ) were calculated by dividing the expected environmental concentration with the ½ EC_{50} value for the most sensitive algae. Based on the screening level assessment, there is a potential risk to algae (risk quotient values ranged from 37 to 154; Level of Concern = 1). A refined assessment was conducted to further characterize the risk from exposure through drift. Risk quotient values ranged from 1 to 119 in the refined risk assessment, indicating a potential risk of concern for non-vascular aquatic plants, including algae.

Hexazinone is infrequently detected in surface water in Canada. The highest concentration of hexazinone detected in Canadian surface water was 11.78 µg/L. Using this maximum value, the risk quotient slightly exceeds the level of concern (RQ = 3.4). Out of a total of nearly 2000 surface water samples, only two samples had hexazinone concentrations that exceeded the level of concern. Based on available data, levels of hexazinone found in Canadian waters are not expected to pose a risk of concern to aquatic non-vascular aquatic plants.

To mitigate potential risk to algae from spray drift, increased aquatic buffer zones are proposed (see Appendix II for details). In addition, all current end-use product labels include a statement indicating toxicity to aquatic species, as well as environmental hazard statements regarding runoff. With the risk reduction mitigation measures, the exposure to algae is not expected to be of concern.

5.0 Proposed Special Review Decision for Hexazinone

Evaluation of available scientific information related to the aspects of concern indicated that the registered products containing hexazinone do not pose risks of concern to human health and the environment with the proposed mitigation measures. On this basis, the PMRA is proposing to confirm the current registration of products containing hexazinone for sale and use in Canada pursuant to subsection 21(1) of the *Pest Control Product Act*, with the proposed label amendments outlined in Appendix II.

This proposed special review decision is a consultation document.[1] The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

6.0 Next Steps

Before making a special review decision on hexazinone, the PMRA will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on hexazinone. The PMRA will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision and the PMRA's response to these comments.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Appendix I Registered Products Containing Hexazinone as of 13 December 2016

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
19544	Technical	Tessenderlo Kerley, Inc	Hexazinone Technical Herbicide	Solid	98.7%
27551	Manufacturing concentrate	Tessenderlo Kerley, Inc	Hexazinone 90SP MUP	Soluble powder	90.0%
29291	Manufacturing concentrate	Tessenderlo Kerley, Inc	Velpar L MUP Herbicide	Solution	240 g/L
29613	Manufacturing concentrate	Tessenderlo Kerley, Inc	Velpar DF MUP	Wettable granules	75.0%
14163	Commercial	Tessenderlo Kerley, Inc	Velpar Weed Killer Herbicide	Soluble powder	90%
18197	Commercial	Tessenderlo Kerley, Inc	Velpar L Herbicide	Solution	240 g/L
21390	Commercial	Tessenderlo Kerley, Inc	Pronone 10G Granular Herbicide	Granular	10%
25225	Commercial	Tessenderlo Kerley, Inc	Velpar DF Herbicide Water Dispersible Granule	Wettable granules	750 g/kg
31766	Commercial	Bayer CropScience Inc	Velpar DF VU Herbicide Water Dispersible Granule	Wettable granules	75.0%
31786	Commercial	Bayer CropScience Inc	Velpar L VU Herbicide	Solution	240 g/L

Appendix II Label Amendments for Products Containing Hexazinone

The label amendments presented below do not include all label requirements for individual products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on the labels of currently registered products should not be removed unless it contradicts the label statements below.

1 Technical and manufacturing concentrates

1) Add the following to a section entitled **ENVIRONMENTAL HAZARDS**

"TOXIC to aquatic organisms"

2) Add the following to the section entitled **PRECAUTIONS**

"DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters."

2 End-use products for all formulations except granular

The labels of all end-use products (except granular) must be amended to include the following statements to further protect the environment.

2.1 For all products registered for use on lowbush blueberry, highbush blueberry and alfalfa

Add to **DIRECTIONS FOR USE:**

"Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) coarse classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air."

2.2 For all products registered uses on woodland management and Christmas Tree plantations

"Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) coarse classification. Boom height must be 60 cm or less above the crop or ground.

Aerial application: **DO NOT** apply during periods of dead calm. Avoid

application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) coarse classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing- or rotorspan."

Buffer zones:

"Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of Application	Crop		Buffer zones (metres) required for the protection of				
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		Terrestrial habitat
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer	woodland management (less than 500 ha)		3	1	2	1	NR
	lowbush blueberry		2	1	1	1	5
	established conifers		2	1	1	1	5
	highbush blueberry		1	1	1	1	5
	established seed and forage alfalfa		1	1	1	1	5
Aerial (SG formulation)	woodland management (less than 500 ha)	Fixed wing	350	175	250	125	NR
		Rotary wing	225	100	150	80	NR
Aerial (SN formulation)	woodland management (less than 500 ha)	Fixed wing	375	200	250	125	NR
		Rotary wing	225	125	150	80	NR

NR: Buffer zones for the protection of terrestrial habitats are not required for use in forestry and woodlot management

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The buffer zones for products containing hexazinone can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site."

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